

### **REMARKS**

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

#### **Claim Amendments**

Claims 1-3, 5-7, 15-18, 21-22, and 24-35 were pending in this application when last examined.

Claims 4, 8-14, 19-20, and 23 were cancelled without prejudice or disclaimer thereto.

Claims 1-3, 5-7, 15-18, 21-22, and 24-35 were examined on the merits and stand rejected.

Claims 3, 15-18, 21-22, and 24-35 are cancelled herein without prejudice or disclaimer thereto.

Claims 1-2 are amended herein to clarify the claimed invention, while claims 36-45 are newly added. Claim 1 clarifies “to a patient in need of improvement of insulin resistance”. Claim 36 clarifies that a patient in need of improvement of insulin resistance is selected from patients. Claim 41 clarifies that a patient is determined as a patient in need of improvement of insulin resistance. Support for these amendments can be found in the claims as originally filed, and, inter alia, in the specification, e.g., paragraphs [0007]-[0008], [0032]-[0033], and [0036]-[0037].

No new matter has been added.

#### **Consideration After Final Rejection**

Although these amendments are presented after final rejection, the Examiner is respectfully requested to enter the amendments and consider the remarks, as they place the application in condition for allowance, and an RCE is filed herewith.

#### **Patentability Arguments**

The patentability of the present invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

**Rejections Under 35 USC 102(b)**

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 2003011308 (WO '308);

Claims 1-3 and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Garg (Ann. Inter. Med., 1994);

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 2002-537390 (JP '390);

Claims 15-16, 21-22, 25-28, 31-32 and 34-35 are rejected under 35 U.S.C. § 102(b) as being anticipated by US 5,468,727;

Claims 15, 17, 21-22, 24, 27, 29 and 31-33 are rejected under 35 U.S.C. § 102(b) as being anticipated by EP 0793960; and

Claims 15, 18, 21-22, 27 and 30-32 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 9841216.

These rejections are respectfully traversed as applied to the amended claims.

**The Position of the Examiner**

The Examiner takes the position that the rejected claims are anticipated for the reasons indicated. Applicants do not acquiesce to the positions of the Examiner.

**The Position of Applicants**

Applicants respectfully disagree with the Examiner's position.

It is initially noted that claim 3-4 and claims 8-35 now stand cancelled herein without prejudice or disclaimer thereto, thereby mooted any rejections directed to these claims.

The patentability of the present invention is supported as follows. The patients of type II diabetes patients are classified as patients who require improvement of insulin resistance and patients who do not require improvement of insulin resistance. In the present invention, a pharmaceutically acceptable anion exchange resin is administered to a patient in need of improvement of insulin resistance. More specifically, the causes of type 2 diabetes include reduced insulin secretion, and reduced insulin sensitivity. In the present invention, a

pharmaceutically acceptable anion exchange resin is administered to a patient of type 2 diabetes showing reduced insulin sensitivity, but is not administered to a patient of type 2 diabetes not showing reduced insulin sensitivity. As mentioned above, the target of administration of the agent of the present invention is a part of type 2 diabetes patients (not all patients of type 2 diabetes).

With regard to the remaining claim rejections, Applicants respectfully submit that the Examiner has not asserted that the cited references anticipate all features of the claims as amended.

For instance, claim 1, and claims dependent thereon, now require that the patient suffers from a disease or symptom of hyperinsulinism, abnormal lipid metabolism, arteriosclerosis, abnormal vascular endothelial function, coronary artery disease, cardiovascular disease, renal dysfunction, hypertension, fatty liver, type 2 diabetes, hyperuricemia, multiple risk factor syndrome or gestational diabetes.

Further, claim 1, and claims dependent thereon, now require that the pharmaceutically acceptable anion exchange resin is selected from the group consisting of colestimide, cholestyramine resin, colestipol, sevelamer hydrochloride, and colesevelam hydrochloride.

The Examiner has not asserted that the cited references anticipate all features of the claims as amended.

For at least these reasons, Applicants respectfully assert that the cited references do not anticipate all material features of the claims as amended herein. Thus, the rejections are untenable as applied to the amended claims and should be withdrawn.

**Conclusion**

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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